JUL 31 2001

8. Summary of Safety and Effectiveness

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K011673.

Submitter:
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121
Phone: 858-535-2030
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Date:
May 16, 2001

Contact Person:
Edward Tung

Product Name:
ACON® AMP One Step Amphetamine Test Strip
ACON® AMP One Step Amphetamine Test Device

Common Name:
Immunochromatographic test for the qualitative detection of amphetamine in urine specimens.

Device Classification:
The ACON AMP One Step Amphetamine Test Strip and ACON AMP One Step Amphetamine Test Device are similar to other FDA-cleared devices for the qualitative detection of amphetamine in urine specimens. These tests are used to provide a preliminary analytical result. (21 CFR 862.3100). Amphetamine test systems have been classified as Class II devices, moderate complexity.

Classification Name:
Amphetamine test system

Intended Use:
The ACON® AMP One Step Amphetamine Test Strip and ACON® AMP One Step Amphetamine Test Device are rapid chromatographic immunoassays for the qualitative detection of amphetamine in human urine at a cut-off concentration of 1,000 ng/mL

Description:
The ACON AMP One Step Amphetamine Test Strip and ACON AMP One Step Amphetamine Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of amphetamine, in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes a monoclonal antibody to selectively detect elevated levels of amphetamine in urine at a cut-off concentration of 1,000 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug negative urine specimen will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

Predicate Device:

LifeSign Status DS™ AMP One-Step Amphetamine Test

510(k) Number K945610

Distributor:
LifeSign
71 Veronica Avenue
Somerset, New Jersey 08873

Comparison to a Predicate Device:
A summary comparison of the features of the ACON AMP One Step Amphetamine Test Strip and ACON AMP One Step Amphetamine Test Device and the LifeSign Status DS™ AMP One-Step Amphetamine Test is shown below.

- Both tests are assays intended for the qualitative detection of amphetamine in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for rapid detection of amphetamine with a visual, qualitative end results.
- Both tests utilize the same basic immunoassay principles that rely on antigen / antibody interactions to indicate a positive or negative result.
- Both tests have a amphetamine cut-off concentration of 1,000 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 specimens. Ten percent of these clinical specimens were either at +25% or –25% levels of the cut-off concentration of 1,000 ng/mL methamphetamine. This evaluation compared the results of the ACON® AMP One Step Amphetamine Test Strip and the ACON® AMP One Step Amphetamine Test Device and the LifeSign Status DS™ AMP One-Step Amphetamine Test to the customary Gas Chromatography/Mass Spectrometry analysis technique. The data from this study yielded the following results:

ACON AMP One Step Amphetamine Test Strip compared to the LifeSign Status DS™ AMP One-Step Amphetamine Test:

Positive Agreement:	141 / 146 = 97%
Negative Agreement:	154 / 154 = 100%
Overall Agreement:	295 / 300 = 98%

ACON AMP One Step Amphetamine Test Device compared to the LifeSign Status DS AMP One-Step Amphetamine Test:

Positive Agreement:	140 / 146 = 96%
Negative Agreement:	154 / 154 = 100%
Overall Agreement:	294 / 300 = 98%

ACON AMP One Step Amphetamine Test Strip compared to GC/MS:

Positive Agreement :	132 / 136 = 97%	(93 - 99%) *
Negative Agreement:	155 / 164 = 95%	(90 - 93%) *
Total Agreement:	287 / 300 = 96%	(93 - 98%) *
PPV (+):	132 / 141 = 94%	(88 - 97%) *
NPV (-):	155 / 159 = 97%	(94 – 99%) *

ACON AMP One Step Amphetamine Test Device compared to GC/MS

Positive Agreement::	131 / 136 = 96%	(92 - 99%) *
Negative Agreement:	155 / 164 = 95%	(90 - 97%) *
Total Agreement:	286 / 300 = 95%	(92 - 97%) *
PPV (+):	131 / 140 = 94%	(88 - 97%) *
NPV (-):	155 / 160 = 97%	(93 - 99%) *

* Denotes 95% confidence intervals

Sensitivity

A drug-free urine pool was spiked with amphetamine to the following concentrations: 0, 500, 750, 1,000, 1,250, 1,500 and 2,000 ng/mL. Each concentration level was tested in replicates of thirty (30) with both the ACON® AMP One Step Amphetamine Test Strip and ACON® AMP One Step Amphetamine Test Device. The data indicate 100% accuracy at 50% above and 50% below the cut-off concentration of 1,000 ng/mL.

Analytical sensitivity of the ACON Amphetamine Test Strip

Amphetamine Concentration (ng/mL)	% Cut-off	n	Visual Result	
			Negative	Positive
Negative urine	0	30	30	0
500 ng/mL	50%	30	30	0
750 ng/mL	75%	30	22	8
1,000 ng/mL	Cut-off	30	12	18
1,250 ng/mL	125%	30	2	28
1,500 ng/mL	150%	30	0	30
2,000 ng/mL	200%	30	0	30

Analytical sensitivity of the ACON Amphetamine Test Device

Amphetamine Concentration (ng/mL)	% Cut-off	n	Visual Result	
			Negative	Positive
Negative urine	0	30	30	0
500 ng/mL	50%	30	30	0
750 ng/mL	75%	30	23	7
1,000 ng/mL	Cut-off	30	9	21
1,250 ng/mL	125%	30	1	29
1,500 ng/mL	150%	30	0	30
2,000 ng/mL	200%	30	0	30

Specificity

Specificity studies were conducted by individually spiking various amphetamine related compounds and metabolites into drug-free urine. These samples were further diluted sequentially to different concentrations until the lowest concentration that yielded a positive result was identified. The following compounds gave positive results at the respective concentrations. The % Cross Reactivity was determined from these concentrations.

Compounds	Concentration (ng/mL)	% Cross Reactivity
D-Amphetamine	1,000	100
L-Amphetamine	50,000	2
D,L-Amphetamine	3,000	33
(+, -) – 3,4- Methylenedioxyamphetamine (MDA)	2,000	50
Phentermine	3,000	33

Interfering Substances

No interference was observed in our studies when using negative or positive specimens (1,500 ng/mL of amphetamine) containing the following substances at a final concentration of 100 ug/mL:

4-Acetamidophenol	Estrone 3 Sulfate	Oxazepam	Trimipramine
Acetaphenetidine	Ethyl –p- aminobenzoate	Oxolinic Acid	Tryptamine
N-Acetylprocainamide	Fenoprofen	Oxycodone	D,L –Tryptophan
Acetylsalicylic acid	Furosemide	Oxymetazoline	Tyramine
Aminopyrine	Gentisic Acid	Promazine	Uric Acid
Amitryptyline	Hydralazine	Promethazine	Verapamil
Amobarbital	Hydrochlorothiazide	D –L - Propanolol	Zomepirac
L-Ascorbic acid	Hydrocodone	D – Propoxyphene	Ampicillin
Amoxicillin	Hydrocortisone	D– Pseudoephedrine	Caffeine
Apomorphine	O-Hydroxyhippuric Acid	Papaverine	(±)Chlorpheniramine
Aspartame	P-Hydroxymethamphetamine	Pennicillin – G	Brompheniramine
Atropine	3-Hydroxytyramine	Pentobarbital	Ranitidine
Benzilic Acid	Ibuprofen	Perphenazine	Cannabinol
Benzoic Acid	Imipramine	Phencyclidine	P-Hydroxyamphetamine
Benzoylecgonine	Iproniazide	Phenelzine	(1R), (2S)- (-)- Ephedrine
Benzphetamine	(-)Isoproternol	Phenolbarbital	(L)- Ephedrine
Bilirubin	Isoxsuprine	L – Phenylephrine	Fenfluramine
Canabidiol	Ketamine	B – Phenylethlamine	3,4- Methylenedioxyethy-amphetamine (MDE)
Chloralhydrate	Ketoprofen	Phenylpropanolamine	(L)- MAMP
Chloramphenicol	Labetanol	Prednisolone	(D)- MAMP
Chlordiazepoxide	Levophenal	Procaine	
Chlorothiazide	Loperamide	Prednisone	
Chlopromazine	Hemoglobin	Quinidine	
Chloroquine	Maprotiline	Quinine	
Cholesterol	Meprobamate	Salicylic Acid	
Clomipramine	Methadone	Secobarbital	
Clonidine	Meperidine	Serotonin	
Codeine	Methoxyphenamine	Sulfamethazine	
Cortisone	(+)3,4Methylenedioxy Methamphetamine	Sulindac	
(-) Cotinine	Methylphenidate	Temazepam	
Creatinine	Morphine-3-B-D-Glucuronide	Tetracyline	
Deoxycorticosterone	Nalidixic Acid	Tetrahydrocortison3 Acetate	
Dextromethorphan	Naloxone	Tetrahydrocortisone-3B-D Glucuronide	
Diazepam	Naltrexone	Tetrahydrozoline	
Diclofenac	Naproxene	Thiamine	
Diflunisal	Niaciamide	Thebaine	
Digoxin	Nifedipine	Thioridazine	
Diphenhydramine	Norcodeine	D,L – Tyrosine	
Doxylamine	Norothindrone	Tolbutamine	
Ecgonine methylester	D-Norpropoxyphene	Trans-2-phenylcyclopropglamine	
(-)Y-Ephedrine	Noscapine	Triamterene	
Erythromycine	D,L Octopamine	Trifluoperazine	
B-Estadiol	Oxalic Acid	Trimethoprime	

Intra and inter-assay variability
Both the ACON® Amphetamine Test Strip and Test Device demonstrated a high level of precision within run, between run and between days.

Conclusion
These studies demonstrate the substantial equivalency of the ACON® AMP One Step Amphetamine Test Strip and ACON® AMP One Step Amphetamine Test Device to the LifeSign Status DS™ AMP One-Step Amphetamine Test, which is already marketed. They further demonstrate the suitability of this product for professional and point-of-care use, in addition to demonstrating their safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 3 1 2001

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: 510(k) Number: K011673
Trade/Device Name: ACON® AMP One Step Amphetamine Test Strip and
ACON® AMP One Step Amphetamine Test Device
Regulation Number: 862.3100
Regulatory Class: II
Product Code: DKZ
Dated: May 16, 2001
Received: May 30, 2001

Dear Dr. Tung:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number: K011673

Device Name: ACON® AMP One Step Amphetamine Test Strip
ACON® AMP One Step Amphetamine Test Device

Indications for Use: The ACON AMP One Step Amphetamine Test Strip and ACON AMP One Step Amphetamine Test Device are rapid chromatographic immunoassays for the qualitative detection of amphetamine in human urine at a cut-off concentration of 1,000 ng/mL. These tests are for professional and point of care use.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011673

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use_____

(Per 21 CFR 801.109)